Federal agency for medicines and health products

Seminar LM4: Falsified Medicines Directive - Did they forget the hospital pharmacy?

Philippe De Buck  23-24 march 2017
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Disclosure

- Conflict of interest : nothing to disclose
Learning objectives

• understand the background, goal and flow of the required tracking system.
• understand the content of the barcode and the (inter)national repositories.
• estimate the impact for the hospital pharmacist when this system is implemented.
• evaluate cost/benefit of the system.

Overview / control questions

All medicinal products will have to carry a 2-D Barcode by 2019

The 2-D Barcode will include batch number and expiry date

All 2-D Barcodes will be stored in one central database
Falsified Medicines:

Not as simple...: Definition FMD

Any medicinal product with a false representation of:
(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
(c) its history, including the records and documents relating to the distribution channels used.
...and not limited to lifestyle medicines

- Erectile dysfunction
- Weight loss
- Alopecia
- ...

Lifestyle

- Antibiotics
- Painkillers
- Antihistamines
- ...

Mainstream

- Cancer treatment
- Antimalarial drugs
- HIV medicine
- ...

Lifesaving

Geographic scope of the problem
Geographic scope of the problem

- **UK 2007**: Casodex, Plavix...
- **Germany 2013**: Omeprazole
- **Romania 2013**: Interferon
- **Italy 2014**: Herceptin
### Action needed!

<table>
<thead>
<tr>
<th>Year</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>Public consultation</td>
</tr>
<tr>
<td>2011</td>
<td>Falsified Medicines Directive</td>
</tr>
<tr>
<td>2011</td>
<td>Concept paper on Delegated Regulation</td>
</tr>
<tr>
<td>2011</td>
<td>Delegated Act on Safety Features</td>
</tr>
<tr>
<td>2019</td>
<td>Implementation</td>
</tr>
<tr>
<td>2019</td>
<td>Packaging adapted</td>
</tr>
<tr>
<td>2019</td>
<td>Repositories (databases) fully operational</td>
</tr>
<tr>
<td>2019</td>
<td>Software adapted</td>
</tr>
<tr>
<td>2019</td>
<td>Safety features are checked</td>
</tr>
</tbody>
</table>

### In practice

**Unique Identifier =**
- Product Code
- Random Serial Number
- Batch number
- Expiry Date

**Encoding**

```
PC : 01234500000001
SN : AX12345S5R64556P35153O1353l2
EXP : 01012020
BATCH : 18A21
```
For which products?

**Whitelist**
- Homeopathic medicines
- Radionuclide generators
- Gases
- ATMP w/tissues or cells
- Some contrast medias
- Some IV solutions
- ....

**Blacklist**
- Omeprazole

**SCOPE**
- UI compulsory for:
  - POM medicines
  - Blacklist products
- UI forbidden for:
  - OTC
  - Whitelist products
- Optional UI:
  - Reimbursed products if member states decide so

**For which products?**
- For which products?

**Distributor**

**Patient**

**Status:** Dispensed

**PC:** 012345000000013N: 1234555845...

**Status:** Dispensed
Anti-tampering device

Same scope as UI
Can be extended by MS
Form: Left to MAH
- Sticker seal
- Shrink wrap
- Glue
- ...

To be checked by pharmacist!

What is the risk/benefit for the hospital pharmacy

Risks
- Increased workload
- Checking can be at reception...
- ...but limits returns (10 days max.)
- Limited ROI
- No provision for bedside scanning
Risk mitigation?

• Delegated Regulation
  – Exceptions on decommissioning
  – Aggregation: decommission “en masse”

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Conclusions/take home message

9th February 2019:

A lot of work for industry…

…but also for the hospital pharmacist

• Adapt software to enable checking
• Adapt workflows and find resources
• Explore possibilities for optimization

Contact

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